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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,341	10/13/2000	Hisakazu Kurita	K0448/7003	5123

7590 08/30/2004

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,341	KURITA ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and request under 1.114, both filed 06/28/2004.

Claims 1-12 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/28/2004 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08-157365 ('365).

JP '365 teaches a transdermal adhesive preparation having remarkable high skin permeation rate and remarkable reduced skin irritation and provides good medicine stability. The preparation comprising 0.1-10 wt.% base drug salt and 0.5-5 wt.% of sodium acetate (abstract; page 1 of the translation, claim 6; page 3, paragraph 009).

The reference does not expressly disclose the organic acid in the powder from or the mean diameter of the powder particles.

However, in the examples pages 6 and 7, paragraphs 0029- 0031, the reference disclosed the components are dissolved except for the sodium acetate, and this suggests the powder form of the sodium acetate. Further the reference disclosed in the same examples that the thickness of the adhesive film that contains the components is

50-100 micrometers, and this implies that the particles size of the powdered organic acid cannot be more than 100 micrometers in diameter.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal adhesive preparation comprising active agent and sodium acetate powder as disclosed by JP '365, and select the sodium acetate having particles size less than 50 micrometers as suggested by the reference, motivated by the teaching of the reference that such preparation has remarkable high skin permeation rate and remarkable reduced skin irritation and provides good medicine stability, with reasonable expectation of having stable transdermal preparation with the contained sodium acetate particles having diameters less than 50 micrometers with high skin permeability rates and reduced skin irritation.

5. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10045570 ('570).

JP '570 teaches percutaneous adhesive preparation that has low skin irritation and excellent skin permeability (abstract). The preparation comprises 0.05 wt.% of active agent and 0.01-15 wt.% of sodium acetate (abstract; claims 1, 2; page 2, 0006, 0008).

The reference does not expressly disclose the organic acid in the powder from or the mean diameter of the powder particles.

However, in the examples page 5, paragraphs 0019- 0021, the reference disclosed the components are dissolved except for the sodium acetate, and this

suggests the powder form of the sodium acetate. Further the reference disclosed in the same examples that the thickness of the adhesive film that contains the components is 50-100 micrometers, and this implies that the particles size of the powdered organic acid cannot be more than 100 micrometers in diameter.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal adhesive preparation comprising active agent and sodium acetate powder as disclosed by JP '570, and select the sodium acetate having particles size less than 50 micrometers as suggested by the reference, motivated by the teaching of the reference that such a preparation has low skin irritation and excellent skin permeability, with reasonable expectation of having transdermal preparation with the contained sodium acetate particles having diameters less than 50 micrometers that highly permeates the skin with minimum irritation.

6. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,866,157 ('157).

US '157 teaches an adhesive composition for matrix patch formulation that improved the permeability of the drug and significantly reduces the skin irritation (col.2, lines 33-36). The composition comprising from 0.1 to 20 % (w/w) of a basic drug and from 0.01 to 15 % (w/w) of organic acid or its salt such as sodium acetate (abstract; col.2, lines 40-60; col.3, lines 9-25, 55-58; examples).

US '157 does not expressly disclose the organic acid in the powder from or the mean diameter of the powder particles.

The reference does not expressly disclose the organic acid in the powder from or the mean diameter of the powder particles.

However, in the examples 1 and 2, the reference disclosed the components are hot melted, i.e. not dissolved, and this suggests the powder form of the sodium acetate. Further the reference disclosed in the same examples that the thickness of the adhesive film that contains the components is 100 micrometers, and this implies that the particles size of the powdered organic acid cannot be more than 100 micrometers in diameter.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal adhesive matrix comprising active agent and sodium acetate powder as disclosed by US '157, and select the sodium acetate having particles size less than 100 micrometers as suggested by the reference, motivated by the teaching of the reference that such a composition for the matrix has improved permeability and significantly reduced skin irritation, with reasonable expectation of having transdermal matrix composition with the contained sodium acetate particles having diameters less than 100 micrometers that highly permeates the skin with minimum irritation.

Applicants' arguments

7. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER